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Development of Maximum Contaminant Levels under the Safe Drinking Water Act

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DEVELOPMENT OF MAXIMUM CONTAMINANT LEVELS UNDER THE SAFE DRINKING WATER ACT

WATER POLICY OFFICE
OFFICE OF WATER
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WPI Development of Maximum Contaminant Levels Under the Safe Drinking Water Act

This report is part of the National Network for Environmental Management Studies conducted under the auspices of the Office of Cooperative Environmental Management —U. S. Environmental Protection Agency. This report follows the legislative history of the Safe Drinking Water Act and provides background information on the strategy used by EPA to establish safe levels of contaminants in drinking water. It is intended to provide an overview of a complex process whereby various criteria are evaluated to set Maximum Contaminant Levels (MCLs). An example is provided to illustrate the stepwise process involved in establishing the MCL for para dichlorobenzene.

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Disclaimer

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PURPOSE OF THIS REPORT

This work was conducted as part of the National Network for Environmental Policy Studies (NNEPS) intern program. The document has been reviewed by personnel in the Office of Drinking Water and the Water Policy Office within the Office of Water at the Environmental Protection Agency (EPA) for accuracy and appropriateness. Viewpoints and opinions expressed do not necessarily represent those of the EPA.

Amendments to the Safe Drinking Water Act (SDWA) in 1986 greatly expanded the list of contaminants for which the EPA must establish safe levels in drinking water. These Maximum Contaminant Levels (MCLs) are developed by the Office of Drinking Water (ODW) at EPA through the application of a number of criteria and procedures. In an effort to develop a clearer understanding of how this process works, research was conducted by a summer intern in the Water Policy Office at EPA on the Safe Drinking Water Act and protocols used in developing regulations for particular contaminants. The information in this report has been compiled from that research.

This paper is intended to provide a descriptive report on the methodology used by EPA to develop MCLs for contaminants in drinking water. It should serve as a useful tool in understanding the approach used to define MCLs and the factors applied in establishing a given number (concentration) for a particular contaminant. Background information on the development of the legislation is provided to enhance the reader's perspective on how the concept of MCLs has changed with recent modifications to the Safe Drinking Water Act.

INTRODUCTION

The Safe Drinking Water Act was passed in 1974 after several years of work by Congress to develop a nationwide program to protect the quality of the country's public water supply system. Until that time, the Public Health Service had developed drinking water standards for several contaminants, though these only applied to interstate carriers of water. Passage of the 1974 legislation placed responsibility for the establishment of national drinking water standards upon the Environmental Protection Agency.

EPA took initial responsibility for enforcement of drinking water regulations. Enforcement duties were then transferred to the States as their drinking water programs were approved and they were given primacy. Primacy requirements include the setting of state standards at least as stringent as those set by EPA. Only a few states have not yet received primacy.

EPA currently establishes Maximum Contaminant Level Goals (MCLGs) for drinking water by setting standards for a level at which "no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." These levels are used to develop Maximum Contaminant Levels (MCLs) which are set as close to the MCLGs as "feasible". Feasible is defined in the Safe Drinking Water Act as "feasible with the use of the best technology, treatment techniques and other means which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration)."

In order to understand how this language was developed and the intention of Congress in the amendments to the SDWA in 1986, excerpts from the legislative history are reviewed and analyzed to provide background.

LEGISLATIVE BACKGROUND

SDWA Prior to the 1986 Amendments

Growing concern over the lack of knowledge about harmful contamination of drinking water and the potential for substantial negative impacts on the human population prompted Congress to amend the Public Health Service Act in 1974. The House Report to Congress on the initial SDWA of 1974 clearly illustrates the intent to protect human health and develop more stringent regulations for drinking water:

> "The purpose of this legislation is to assure that water supply systems serving the public meet minimum national standards for protection of public health."

Primary drinking water standards were intended to protect the public "to the maximum extent feasible" and the Administrator of EPA was charged with identifying contaminants which "have an adverse effect on the health of persons." This language is further clarified by the Committee on Interstate and Foreign Commerce in the following excerpt:

> "...the Committee did not intend to require conclusive proof that any contaminant *will* cause adverse effects as a condition for regulation of a specific contaminant. Rather, all that is required is that the Administrator make a reasoned and plausible judgement that a contaminant *may* have such an effect."

That judgement is to be based on "epidemiological, toxicological, physiological, biochemical, or statistical research or studies or extrapolations therefrom." This broad based discretion enables the Administrator to use a number of criteria in developing the list of contaminants and was intended to allow for regulation of groups of chemicals as well as specific constituents.

Once the list of contaminants has been developed, it is necessary to develop an actual number which serves as the national standard for a particular contaminant. The House Report states:

> "The only circumstance in which a maximum contaminant level is not to be prescribed is if he (the Administrator) finds

> that it is not technologically or economically feasible for most public water systems to monitor for that contaminant."

If such a finding is made, the Administrator is then required to list all known treatment technologies which remove that contaminant and require that at least one of those technologies be employed by the public water system. This forms a two stage process whereby an MCL for a contaminant is specified, or if such determination cannot be made, a technology is then prescribed which is known to effectively control for that contaminant (in lieu of an actual number). The standard/technology approach remains the backbone of the SDWA, with priority placed on the protection of public health.

The House Committee felt that inadequate information on health effects of contaminants in drinking water was a deficiency which called for more scientific study. The 1974 Act mandated that the Administrator arrange with the National Academy of Sciences (NAS) to conduct studies on the maximum contaminant levels which should be allowed in drinking water. Congress further specified "the NAS is directed to consider only what is required for protection of public health, not what is technologically or economically feasible or reasonable." The consideration of feasibility was left to the EPA:

> "Economic and technological feasibility are to be considered by EPA and then only for the purpose of determining how soon it is possible to reach recommended maximum contaminant levels and how much protection of the public health is feasible until then."

Information from the study done by the NAS was then to be used by EPA to establish Recommended Maximum Contaminant Levels (RMCLs). The RMCLs were intended to be health goals which would "prevent the occurrence of any known or anticipated health effects with an adequate margin of safety." Language in the House Report delineates the difference between "adequate margin of safety" and "known or anticipated health effects". It directs the Administrator to establish RMCLs by a three step process:

- "The known adverse health effects of contaminants are to be compiled."
- "The Administrator must decide whether any adverse effects can be reasonably anticipated, even though not proved to exist. [It is at this point that the Administrator must consider the possible impact of

synergistic effects, long-term and multi-media exposures, and the existence of more susceptible groups in the population.]"

- "The recommended maximum contaminant level must be set to prevent the occurrence of any known or anticipated adverse effect."

If unable to establish a safe threshold for a particular contaminant, it was specified that the RMCL for that contaminant should be set at zero. This is in accordance with the requirement to include an adequate margin of safety in setting the RMCL.

It was required that revised national drinking water regulations be proposed at the time of promulgation of RMCLs. These revised regulations were to "specify the contaminant level (or treatment methods if monitoring is infeasible) which provides maximum feasible protection for human health, using generally available methods of treatment or control."

In gauging how the Safe Drinking Water Act was implemented and the initial progress made after its passage, it is worthwhile to examine the testimony of Thomas C. Jorling during hearings on reauthorization of SDWA in 1979. Jorling was then Assistant Administrator for Water and Waste Management at EPA. At that time, the States were doing well in revising their laws and meeting federal guidelines to achieve primacy. In March of 1979, forty states had received primary enforcement responsibility and five more were expected to achieve that status before the end of the year. While Jorling accentuated the progress that had been made, he pointed out that "the legislatively mandated research and other studies have clearly established that we are a long way from eliminating all concerns about drinking water."

Another point which was highlighted was the recognition that organic chemicals constituted one of the major threats to health from drinking water:

> "About one-half of our research has been invested in monitoring techniques, health effects, control technology and costs, and economic impacts related to the control of organic contaminants in drinking water."

Mention was made of the use of Granular Activated Carbon (GAC) as a control technology which would effectively remove organics. The inability to determine specific standards for a number of organics

focused attention on the requirement of control technology instead of a maximum contaminant level.

Commenting on the work of the NAS in developing health effects information, Jorling said "...we must rely primarily on the generally accepted scientific interpretation of the results of animal feeding studies." Information from animal studies remains an important facet in the development of MCLs today.

The SDWA Amendments of 1986

The expanding list of contaminants in drinking water and acknowledgement of their potential threat to public health created an urgency to regulate them more comprehensively. This was the basic theme underlying the changes which Congress made to the SDWA in 1986. A review of the legislative history illustrates a dissatisfaction on the part of several congressmen regarding the speed with which EPA was promulgating regulations. Senator Durenberger wrote in the Conference Report:

> "It is now 12 years later (since passage of the 1974 Act) and the Safe Drinking Water Act once again comes to the floor of the Senate with most of the original promise unfulfilled. ...the Environmental Protection Agency has set standards for only a handful of contaminants..."

In the Senate Committee's discussion of the SDWA Amendments of 1986, it is clear that the objective of changes in the law was to expedite the process of establishing standards. Furthermore, a review process was designed to "make them (regulations) more protective of public health whenever possible." The Committee added a clarification on the use of technology to insure adequate protection of public health from drinking water:

> "While cost and technology are factors to be considered in establishing maximum contaminant levels under the Act, the first priority of the Act is to protect human health by reducing or preventing human exposure to potentially harmful contaminants in drinking water."

The House Committee's version of the bill did not differ substantially from that of the Senate. Under the "Basis for standard setting" section, the House amendment included a requirement that

the Agency use adsorption techniques such as granular activated carbon (GAC) in defining best available technology which is feasible for the control of synthetic organic chemicals (SOCs) for purposes of establishing an MCL. The conference agreement incorporated this language with that from the Senate and provided that any treatment technology for the control of SOCs be at least as effective as GAC.

Summary of Key Changes

The congressional intent underlying the SDWA amendments has been discussed briefly. Substantive changes which have relevance to the methodology of setting MCLs are listed below. A summary of each of those changes is then included.

1. Mandatory deadlines set for the regulation of 83 key contaminants.
2. Substitutions are allowed for seven of the 83 contaminants on the list.
3. A change in the use of the term "Best Technology Generally Available" to "Best Available Technology".
4. Elimination of study done by the NAS and addition of review of regulations by the Science Advisory Board (SAB).
5. Change in language from "Recommended Maximum Contaminant Level" (RMCL) to "Maximum Contaminant Level Goal" (MCLG).
6. Proposal of MCLG and MCL at the same time.
7. Establishment of a benchmark for treatment technologies.
8. Periodic review of regulations.

1. Congress established deadlines for the promulgation of regulations for 83 contaminants which were taken from a list which EPA had been working on. The schedule for setting MCLGs and promulgation of national primary drinking water regulations is as follows:

A) Not later than 12 months after the enactment of the Safe Drinking Water Act Amendments of 1986 for not less than 9 of those listed contaminants;
B) not later than 24 months after such enactment for not less than 40 of those listed contaminants;

C) not later than 36 months after such enactment for the remainder of such listed contaminants.

2. Congress recognized that EPA might find contaminants not on the list which posed a greater immediate threat to public health than those for which the deadlines applied. EPA was therefore allowed to substitute as many as seven contaminants for any of those on the list. If a contaminant is substituted, the schedule for the one it replaces applies to the substitution.

3. The original SDWA used the language "generally available" in reference to the type of technology to be considered for removal of contaminants. The amendments deleted this reference and directed the Administrator to consider the "best technology, treatment techniques and other means after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration)."

4. The role of the National Academy of Sciences was changed from actually conducting scientific studies to providing guidance to the Agency as EPA conducts risk assessments and establishes MCLGs. The amended Act also requires that "The Administrator shall request comments from the Science Advisory Board (established under the Environmental Research, Development, and Demonstration Act of 1978) prior to proposal of a maximum contaminant level goal...". These comments are to be considered by EPA but review by SAB may not be used to delay final promulgation of a standard.

5. "Recommended Maximum Contaminant Levels" (RMCLs) were changed to "Maximum Contaminant Level Goals" (MCLGs) to reflect the health goal nature with which they are established. The language change did not functionally change their meaning.

6. Under the 1974 SDWA, EPA issued RMCLs prior to promulgating final MCLs. The 1986 Amendments require that MCLGs and MCLs be proposed and finalized at the same time.

7. The Act as amended specifies that granular activated carbon is available for the removal of synthetic organic compounds. This establishes a benchmark for other technologies which must be at least as effective as GAC.

8. Besides reviewing regulations every 3 years, EPA is directed under the new law to "include an analysis of innovations or changes in technology, treatment techniques or other activities that have occurred over the previous 3-year period and that may provide for greater protection of the health of persons."

These changes have direct and indirect impact on the way in which maximum contaminant levels are developed. Specific

language from the Safe Drinking Water Act, 1986 (as amended) is reprinted below to illustrate portions of the law which direct EPA on the criteria to be used in establishing MCLs.

MCL Determination from the SDWA, 1986 (as amended)

Part A--Definitions

Section 1401

(1) The term "primary drinking water regulation" means a regulation which--

(B) specifies contaminants which, in the judgement of the Administrator, may have any adverse effect on the health of persons;

(C) specifies for each contaminant either--

i) a maximum contaminant level, if, in the judgement of the Administrator, it is economically and technologically feasible to ascertain the level of such contaminant in water in public water systems, or

ii) if, in the judgement of the Administrator, it is not economically or technologically feasible to ascertain the level of such contaminant, each treatment technique known to the Administrator which leads to a reduction in the level of such contaminant sufficient to satisfy the requirements of section 1412.

(3) The term "maximum contaminant level" means the maximum permissible level of a contaminant in water which is delivered to any user of a public water system.

(6) The term "contaminant" means any physical, chemical, biological or radiological substance or matter in water.

Part B--Public Water Systems

Section 1412--National Drinking Water Regulations

(b)(4) Each maximum contaminant level goal established under this subsection shall be set at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety. Each national primary drinking water regulation for a contaminant for which a maximum contaminant level goal is established under this subsection shall specify a maximum level for such

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> contaminant which is as close to the maximum contaminant level goal as is feasible.
> (5) For the purposes of this subsection, the term "feasible" means feasible with the use of the best technology, treatment techniques and other means which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration).
> (7)(A) The Administrator is authorized to promulgate a national primary drinking water regulation that requires the use of a treatment technique in lieu of establishing a maximum contaminant level, if the Administrator makes a finding that it is not economically or technologically feasible to ascertain the level of the contaminant.

These excerpts represent significant portions of the law which have relevance to the setting of MCLs.

ESTABLISHING AN MCL

Application of MCLs to Regulation

As previously cited, the Safe Drinking Water Act requires that EPA establish Maximum Contaminant Level Goals (MCLGs) "at the level at which no known or anticipated adverse effects on the health of persons occur and which allow an adequate margin of safety." These are health based **goals** and are non-enforceable. Maximum Contaminant Levels (MCLs), on the other hand, are enforceable **standards** developed from the MCLGs and set as close to them as feasible. Whereas MCLGs consider only potential health effects, MCLs are set by taking into account the best technology available and the cost of implementing that technology. To understand how MCLs are developed, it is first necessary to understand the procedure for establishing MCLGs.

Setting MCLGs

EPA bases MCLGs on available health effects information which indicates whether or not a particular contaminant causes cancer. Consideration of the potential health effects of a chemical includes the suitability of available data for assessing toxicity and the possibility of human health concern from exposure to the chemical in drinking water. For substances considered to be "known" or "probable" carcinogens, EPA sets the MCLGs at zero. For substances which are considered "possible" carcinogens, EPA sets MCLGs based on chronic toxicity data with an additional margin of safety or on noncarcinogenic risk models.

EPA guidelines for risk assessment include a classification system for chemicals based on evidence of carcinogenicity. This system arranges categories of chemicals into five separate groups:

Group A: Human Carcinogen

This group denotes chemicals for which there is sufficient evidence from epidemiological studies that a causal connection exists between exposure to the chemical and cancer.

Group B: Probable Human Carcinogen

This group is further subdivided into groups B1 and B2.

B1: Used to designate agents for which there is "limited" evidence of carcinogenicity from epidemiologic studies and includes agents for which animal evidence is sufficient.

B2: Used to designate agents for which there is sufficient evidence from animal studies but inadequate or no data from epidemiologic studies.

Group C: Possible Human Carcinogen

This group is used for agents which show limited evidence of carcinogenicity in animals in the absence of human data. Specific evidence might include any of the following:

a) malignant tumor response in a well-conducted experiment that does not meet conditions for sufficient evidence.

b) tumor responses of marginal statistical significance in studies having inadequate design or reporting.

c) benign tumors with an agent showing no response in a variety of short-term tests for mutagenicity.

d) responses of marginal statistical significance in a tissue known to have a high or variable background rate.

Group D: Not Classified

This group is used for agents for which there is inadequate human and animal evidence of carcinogenicity or for which no data is available.

Group E: Evidence of Non-carcinogenicity for Humans

This group is used for agents which show no evidence of carcinogenicity in at least two animal studies or in both adequate epidemiologic and animal studies.

In setting MCLGs, EPA uses a three category approach which incorporates the groups described above:

CATEGORY I--used for chemicals which show strong evidence of carcinogenicity (Group A and Group B).

CATEGORY II--used to designate those chemicals for which there is equivocal evidence of carcinogenicity (Group C).

CATEGORY III--used to set MCLGs for chemicals for which there is inadequate or no evidence of carcinogenicity (Group D and Group E).

CATEGORY I

EPA originally considered three options for setting MCLGs for carcinogens. They were: 1) set the MCLGs at zero, 2) set the MCLGs at the analytical detection limit and 3) set the MCLGs at a non-zero level based upon calculated negligible contribution to lifetime risk. Based upon EPA's analysis and public comments, the Agency chose to set MCLGs for Category I contaminants at zero. Setting the MCLG at zero is based on the fact that there is no demonstrated threshold for carcinogenic health effects. EPA's rationale lies in the mandate of the SDWA which requires that MCLGs be established "at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." Since no threshold can be established for carcinogens, setting the MCLG at zero is considered to fulfill the congressional mandate to provide an "adequate margin of safety."

CATEGORY II

Category II includes contaminants for which there is some limited evidence of carcinogenicity from animal studies. MCLGs are set based upon non-carcinogenic toxicity data (the DWEL) divided by an additional uncertainty factor to account for potential carcinogenic risk.

CATEGORY III

For contaminants where there is inadequate or no evidence of carcinogenicity, MCLGs are set by using a "no-effect" level or Reference Dose (RfD). The RfD is used to set MCLGs for both Category II and III contaminants and is calculated for chronic periods of exposure, including a margin of safety. The RfD is then used to calculate a Drinking Water Equivalent Level (DWEL), which represents a medium specific (drinking water) lifetime exposure at which non-carcinogenic health effects are not anticipated to occur.

Definitions of terms are provided below and the procedure for setting MCLGs for CATEGORY II and III contaminants follows:

RfD--formerly termed the Acceptable Daily Intake (ADI), the RfD represents a no-effect level for chronic periods of exposure to a contaminant from all sources. It is measured in units of mg./kg./day.

No-observed-adverse-effect-level (NOAEL)--this term represents the level of contaminant, after a period of exposure, at which there is no adverse effect observed in laboratory studies of animals or occupational/experimental results from humans. It is based on the principle that most biological effects of chemical substances occur after some threshold dose has been reached.

Lowest-observed-adverse-effect-level (LOAEL)--similar to the NOAEL, it represents the lowest level of contaminant, after a period of exposure, at which there is some observed adverse effect.

Uncertainty factor--because the NOAEL and the LOAEL are often based on scientific studies of animal populations which are subject to variability, these values are usually divided by some uncertainty factor to account for their indefinite nature. Uncertainty factors are used to adjust for intra/interspecies variability, the small number of animals tested compared to the size of the exposed population, sensitive subpopulations, and possible synergistic effects between chemicals. The magnitude of uncertainty factors varies according to the nature of the data from which the NOAELs and LOAELs are derived. A summary of the guidelines used to determine uncertainty factors is taken from the November 13, 1985 proposal for National Primary Drinking Water Standards for Synthetic Organic Chemicals (50 FR 46946):

Uncertainty Factor	Guideline
10	Used with valid experimental results on appropriate durations of exposure in humans.
100	Used when human data are not available and extrapolating from valid results of long-term studies in animals.
1000	Used when human data are not available and extrapolating from studies in animals of less than chronic exposures.
1-10	Additional uncertainty factor applied when using a LOAEL instead of a NOAEL.

DWEL--the drinking water equivalent level converts the reference dose to a concentration level in water by factoring in the

weight of an adult (70 kg.) at a consumption level of 2 liters of water per day.

RSC--the relative source contribution is the proportion of a contaminant contributed by a particular source (water) relative to other sources (air and food).

Reference Dose (RfD) and Drinking Water Equivalent Level (DWEL) Calculation:

$$\text{RfD} = \frac{\text{(NOAEL or LOAEL)}}{\text{(Uncertainty Factor[s])}} = ____ \text{ mg./kg. body wt./day}$$

The RfD is then used to calculate a Drinking Water Equivalent Level (DWEL) which assumes 100% exposure (to a contaminant) from drinking water. The DWEL is calculated as follows:

$$\text{DWEL} = \frac{\text{(RfD) (Body weight in kg.)}}{\text{(Drinking water volume in liters/day)}} = ____ \text{ mg./liter}$$

Where:

Body weight = assumed to be a 70 kg. adult.
Drinking water volume = assumed to be 2 liters/day for an adult.

MCLG Calculation:

Finally, an MCLG is calculated by subtracting from the DWEL any contribution from other sources of exposure such as air or food. If sufficient data on the Relative Source Contribution (RSC) of each of these media is available, then the MCLG is calculated as follows:

$$\text{MCLG} = \text{(DWEL)} - \text{\% contribution from food} - \text{\% contribution from air}$$

If sufficient data are not available on RSCs, the MCLG is set by using an estimate of the drinking water contribution:

$$\text{MCLG} = \text{(DWEL)} \times \text{\% drinking water contribution}$$

The % drinking water contribution is an estimate based on professional judgement. Good data is generally available for inorganic chemicals based on studies by the Food and Drug Administration (FDA) and other surveys. Data for organic chemicals is usually not available. EPA typically uses a value of 20% for the RSC where adequate data is not available. This is considered to be reasonably conservative and protective of pubiic health. Where available data suggest a higher relative source contribution for a particular contaminant, the value of 20% is adjusted upwards to reflect a greater contribution from drinking water.

Where drinking water is responsible for all of the exposure, EPA assigns an RSC of 80%. The use of an 80% "ceiling" is considered to allow for the contingency of exposure via air, food and other sources that may not be reflected in the available data. EPA is considering a 20% "floor" for relative source contributions when the RSC is between 0 and 20%. The Agency feels that a more stringent MCLG based on an RSC below 20% would not result in increased health benefits, since most of the exposure to the contaminant is from other sources.

Summary

Carcinogens

- MCLGs for carcinogens are set at zero.

Non-carcinogens

- MCLGs are set by utilizing a "no-effect" Reference Dose.
- The RfD is used to calculate a Drinking Water Equivalent Level.
- The Relative Source Contribution for the contaminant is applied to the DWEL and an MCLG is calculated.

Setting MCLs

As noted earlier, EPA is required to set MCLs as close to MCLGs as is feasible. In considering what the best available technology is to set a particular MCL (what is feasible), EPA is allowed to select any treatment technology which has been demonstrated to be effective for removal of the contaminant beyond laboratory testing (under field conditions). In establishing an MCL, EPA includes consideration of a variety of factors. These include:

Treatment Technology and Cost

- availability and performance of BAT
- costs of specific technologies to large water systems with relatively clean intake water
- the number of water systems which would be required to install a particular technology

Monitoring

- availability of analytical methods and reliability of analytical results

Health Effects

- health effects are examined as a check on feasibility to assure that MCLs are set at safe levels

Treatment Technology and Cost

EPA examines treatment technologies available for removal of contaminants and evaluates them for a number of criteria. These include:

- removal efficiency based on relatively clean intake water
- degree of compatibility with other water treatment processes
- service life
- ability to achieve compliance for all the water in a public water system

In the final rule for control of volatile synthetic organic chemicals (VOCs), EPA recommended the use of granular activated carbon (GAC) and packed tower aeration (PTA) as the best technology for removal of VOCs from drinking water. These

technologies met the above criteria and had been demonstrated to be effective in the field.

Costs are taken into consideration by analyzing the financial burden of implementing a technology on large public water suppliers. The legislative history of the SDWA indicates that EPA is to consider whether a particular technology is "reasonably affordable" to large metropolitan water systems.

In the VOC rule, it was concluded that GAC and PTA were in fact affordable by public water systems. For VOC contaminants which belonged to carcinogenicity groups C, D and E, MCLGs had been set at the non-zero level. Because the treatment technologies available were capable of removing contaminants below the MCLG, the MCL was set at the same level as the MCLG.

For contaminants which had MCLGs set at the zero level (groups A and B), EPA explored the feasibility of setting various MCLs based on "nationwide costs" and concluded that the costs associated with additional removals (in this case from .005 mg./liter to .001 mg./liter) did not warrant setting the MCL at a lower level.

Monitoring

EPA considers the analytical methods available for the measurement of contaminants and factors this analysis into the process of setting MCLs. They use a method detection limit (MDL) to determine the minimum concentration of a substance which can be measured and reported at the 99% confidence level. The MDL for a particular contaminant is determined by an evaluation of the detection level achievable by a few of the most experienced laboratories under research conditions.

MDLs are used by EPA to determine another analytical benchmark known as the practical quantitation level (PQL). The PQL was defined in the November 1985 proposal (previously cited) as the "lowest level that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions." The basis for EPA determination of a PQL includes the following:

- quantitation
- precision and accuracy
- normal operations of a laboratory
- the fundamental need to have a sufficient number of laboratories available to conduct analyses

The rationale behind the use of a PQL is that it provides a uniform measurement concentration which is laboratory independent and can be used to set standards. EPA has typically estimated the PQL at five to ten times the MDL. The range of five to ten times the MDL has been confirmed from laboratory data to be one in which attainment of reliable data can be achieved. The PQLs are based on multi-laboratory data which are considered to be representative of performance by the best laboratories.

The MDLs for eight of the VOCs fell within the range of .0002 to .0005 mg./liter. Multiplying these values by five to ten results in a range of .001 to .005 mg./liter. The PQL of .005 mg./liter for these VOCs was based on a laboratory performance criterion of $\pm$ 20 percent or 40 percent, depending on the concentration of the contaminant.

Health Effects

Health risks posed by a contaminant are examined at various levels of that contaminant in drinking water. These include health risks for cancer causing agents as well as non-carcinogens. EPA establishes the upper limit unit risk estimate from a linearized multistaged nonthreshold extrapolation model, using data obtained from human and animal studies. The upper 95% target reference risk range for carcinogens is from 10^{-4} to 10^{-6}. This means that a 70 kg. adult consuming two liters of water per day over a lifetime of 70 years would have not more than a 1 in 10,000 and 1 in 1,000,000 chance of getting cancer.

EPA concedes in the proposed VOC rule that risk assessment is an imprecise science:

> "...quantitative risk extrapolation procedures can provide only a rough estimate of carcinogenic hazard because of the many unknown factors which enter into these estimates. Models using different assumptions may produce estimates ranging over several orders of magnitude."

EPA considers the procedures used to assess health risks conservative. They feel that the estimates produced err on the side of overprotection rather than on the side of inadequate protection of public health.

Example: MCLG/MCL Determination for Para-dichlorobenzene (p-dcb)

On November 13, 1985, EPA promulgated an MCLG (then an RMCL) for p-dcb as a Group D substance. This was based on chronic toxicity data from studies available at the time. Following this proposal, EPA received new information from a study on p-dcb conducted by the National Toxicology Program (NTP). The study reported tumors in rats and mice after long term exposure to p-dcb. The results were statistically significant. On April 17, 1987, EPA reproposed the MCLG for p-dcb. Their calculation of the MCLG and MCL were as follows:

MCLG:

New information resulted in a reclassification of p-dcb as Group B2, probable human carcinogen (Category I). MCLGs for Category I contaminants are set at zero, thus the proposed MCLG for p-dcb was established at zero:

MCLG = 0

MCL:

The proposed MCL for p-dcb was determined by the following analysis:

Treatment Technology and Cost

- PTA and GAC adsorption met the engineering criteria for BAT and were considered "best".
- GAC: Costs for up to 99% removal of p-dcb (from 0.5 mg./liter to 0.005 mg./liter) ranged from 7 cents to 15 cents per 1,000 gallons for large to medium systems and were approximately 58 cents per 1,000 gallons for small systems.

PTA: Removal costs were from 5 cents to 8 cents per 1,000 gallons for large to medium systems and 57 cents per 1,000 gallons for small systems.

These costs were considered reasonable by EPA.

Monitoring

- Based on analytical methods for detecting p-dcb, EPA determined that the range for the method detection limit (MDL) was 0.0002 to 0.0005 mg./liter.
- A PQL of 0.005 mg./liter was determined, which confirmed the general rule of a PQL being set at five to ten times the MDL.

• The PQL was established based on a precision of ± 20 percent by most laboratories.

Health Effects

• The draft theoretical upperbound lifetime risk using the conservative linear nonthreshold model (upper 95% confidence level) was between 10^{-5} and 10^{-6} at an MCL of 0.005 mg./liter.

Based on the above analysis, EPA proposed the MCL at 0.005 mg./liter:

MCL = 0.005 mg./liter

Final MCLG and MCL for p-dcb

The proposed MCLG and MCL considered p-dcb as a Group B2 substance. EPA acknowledged that there was controversy surrounding this classification based on the nature of the study by NTP and the applicability of results to humans. They presented a Group C classification as an alternative. Public comments were solicited as to which classification was appropriate. EPA made a judgement based on the weight of the evidence available and concluded that p-dcb should be classified as Group C, possible human carcinogen. Based on this new classification, the MCLG and MCL were calculated as follows:

A reference dose was calculated by using available information from laboratory studies on rats and mice. The RfD was based on a subchronic gavage study.

MCLG:

$$\text{RfD} = \frac{\text{NOAEL}}{\text{(Uncertainty factor)}} = \frac{\text{(150 mg./kg./day) (5)}}{\text{(1000) (7)}}$$

= 0.107 mg./kg./day

[the (5) and (7) come from a dosage which was administered for 5 days out of 7 days per week]
[the uncertainty factor of 1000 was used because data was from a study with less than chronic exposure levels]

$$\text{DWEL} = \frac{(\text{RfD})\,(\text{Body weight})}{(\text{daily consumption of water})} = \frac{(0.107\ \text{mg./kg./day})(70\ \text{kg.})}{2\ \text{liters/day}}$$

$$= 3.75\ \text{mg./liter}$$

$$\text{MCLG} = \frac{(\text{DWEL})\,(\text{RSC})}{(\text{Additional Uncertainty factor})\ [\text{due to Group C classification}]} = \frac{(3.75\ \text{mg./liter})\ (.2\ [20\%])}{(10)}$$

$$= 0.075\ \text{mg./liter}$$

MCL:

The MCL was then established by setting it as close to the MCLG as feasible. Because the recommended treatment technologies (GAC or PTA) were capable of removing contaminants to a level below the MCLG, it was feasible to set the MCL equal to the MCLG.

MCL = 0.075 mg./liter

GLOSSARY OF ACRONYMS

ADI--Acceptable Daily Intake

BAT--Best Available Technology

DWEL--Drinking Water Equivalent Level

EPA--Environmental Protection Agency

GAC--Granular Activated Carbon

LOAEL--Lowest-observed-adverse-effect-level

MCL--Maximum Contaminant Level

MCLG--Maximum Contaminant Level Goal

MDL--Method Detection Limit

NAS--National Academy of Sciences

NOAEL--No-observed-adverse-effect-level

NTP--National Toxicology Program

ODW--Office of Drinking Water

PQL--Practical Quantitation Level

PTA--Packed Tower Aeration

RfD--Reference Dose

RMCL--Recommended Maximum Contaminant Level

RSC--Relative Source Contribution

SDWA--Safe Drinking Water Act

SOC--Synthetic Organic Chemical

VOC--Volatile Synthetic Organic Chemical

WPF

REPORT ON THE RESEARCH ACTIVITIES OF THE OCEAN SURVEY VESSEL *ANDERSON* IN RHODE ISLAND SOUND AUGUST 15-18, 1988



WATER POLICY OFFICE
OFFICE OF WATER
U.S. ENVIRONMENTAL PROTECTION AGENCY

Peyton Robertson
Summer Intern, 1988

BACKGROUND

The Peter W. Anderson is an Ocean Survey Vessel (OSV) used by the Environmental Protection Agency for research in marine and estuarine waters of the United States. Originally a Navy patrol gunboat (USS Antelope PG-86), the vessel was converted for a new mission of environmental research and monitoring in 1979. The Anderson is used primarily for EPA surveys in the offshore waters of the eastern United States. This work includes study of existing and proposed dredge spoil disposal sites as well as monitoring of the 106 mile sewage sludge disposal site (106 miles offshore of the coast of New York and New Jersey). Individual EPA Regional offices are allotted time aboard the Anderson to conduct research pertaining to specific topics in their region.

On December 23, 1986, EPA Headquarters delegated responsibility to the Regional offices for the designation of ocean dumping sites for dredged material. It was intended that this delegation of authority would improve local coordination between EPA, the Army Corps of Engineers, states and local governments. To further expedite the designation of ocean disposal sites, EPA began negotiating a national Memorandum of Understanding (MOU) with the Corps of Engineers in 1986.

RESEARCH CRUISE IN RHODE ISLAND SOUND

As part of the preliminary stage of designating a site for dredge spoil disposal, EPA Region I in cooperation with the Army Corps of Engineers and State of Rhode Island conducted research in the waters of Rhode Island Sound between August 15 and August 18, 1988. The purpose of this work was to establish baseline information on the status of sediments and marine resources in areas which could potentially be designated for dredge disposal. The initial data will be used to narrow the list of potential sites. Further research will be conducted on this smaller list of sites to more comprehensively evaluate their suitability for disposal.

Richard Pastore of the Water Quality Branch, EPA Region I served as chief scientist for the cruise and directed sampling and data collection while the Anderson was underway. The first day of sampling was to be conducted on Monday, August 15, 1988. The Anderson proceeded from a dock in Davisville, Rhode Island through the West Passage of Narragansett Bay to the coastal waters of Rhode Island Sound (see attached map). After two hours of transit time from Davisville, the Anderson was on station for the first sediment sample.

Windblown waves from the southwest had created seas of ten to twelve feet on Rhode Island Sound. The box corer for sediment sampling on the Anderson is deployed over the stern of the ship through a hydraulic A-frame. Because the gear is heavy, rough seas created a potentially dangerous situation and the captain and chief scientist decided to return to Davisville.

The second day, the Anderson returned to the survey area and seas had abated substantially. The box corer was lowered over the stern and sediment samples were taken. The ship continued sampling along a transect in waters between 180 and 200 feet deep. Each box core was dumped into a sediment tray and sub-sampled for three cores. These cores were taken by pushing 2 x 6 inch polycarbonate tubes into the sediment, capping the tubes at both ends, and refrigerating the samples for future analysis. The analysis will involve grain size and sediment chemistry.

The third and fourth day, the Anderson returned to the previously sampled transects to pull otter trawl tows for groundfish and benthic fauna. Tows were conducted for twenty minutes using a twenty foot otter trawl net. Tows were brought onboard and separated by species. Individual species were counted and weighed. Typical animals included fluke, summer and winter flounder, hake, skate and lobster. Species composition, size and distribution will be used to assess impacts of dredge disposal on marine life in the area.

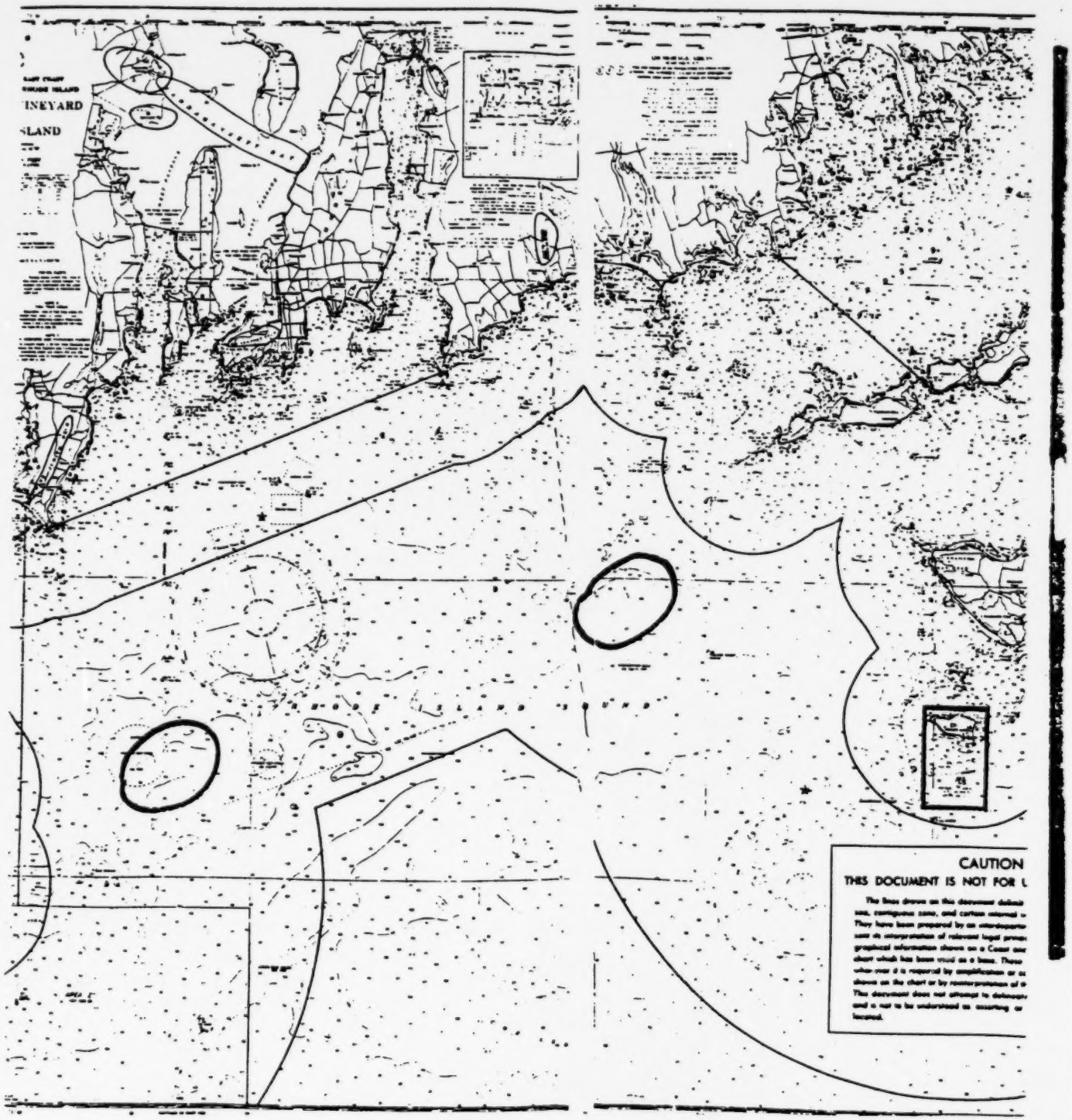
OBSERVATIONS

The cruise provided a unique opportunity to gain an understanding of a typical research mission aboard the OSV Anderson. The Anderson is equipped with state-of-the-art research equipment and is capable of detailed oceanographic analysis. Such sophistication enabled this observer the opportunity to comprehensively understand the area of study. The captain and crew were competent and courteous. The ship was well maintained and though minor difficulties were experienced in deploying some of the gear, the crew responded effectively and minimized delays.

It was interesting to see EPA, Army Corps and State personnel working cooperatively. Collection of information with representative staff from different offices seems to facilitate a better understanding of the site designation process. I was impressed by the knowledge of those aboard and their willingness to assist in any facet of the operation.

Site designation for dredge spoil involves a number of steps. This research cruise was only the first of those steps and further analysis will be necessary. Given the recent press attention to ocean dumping, final designation for the sites in Rhode Island Sound seems unlikely. The proximity to Block Island and Newport, with potential impacts on tourism and commercial fishing, raise the political specter of the issue. The lack of economic resources to dredge harbors is also likely to lessen the immediate need for a new disposal area. These factors lead one to conclude that any new dredge disposal site in the waters of Rhode Island Sound will remain on the drawing board.

SURVEY AREAS FOR POTENTIAL DREDGE DISPOSAL SITES IN RHODE ISLAND SOUND



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FACT SHEET
MARINE DEBRIS

Office of Marine and Estuarine Protection
Office of Water
August 1988

*What is **Marine Debris**?*

Marine debris describes a wide variety of floating material which may eventually end up on shorelines and beaches. The list includes plastic, glass, rubber, styrofoam, metal, paper, wood, and cloth. The most familiar of these items are also the most visible since they destroy the beauty of our waterways and coastlines and harm marine life. Beverage containers, wood debris, packaging material, six-pack yokes, tampon applicators, condoms, discarded fishing gear, garbage bags and plastic dishware represent familiar items found washed up on the beach. Not as noticeable are polyethylene pellets and polystyrene spherules which are the broken down components of styrofoam. These particles can remain floating on the surface for long periods of time and pose unique threats to bird life and waterfowl.

*Where does **Marine Debris** come from?*

Marine debris comes from many sources which are often difficult to identify. Solid waste (garbage) landfills adjacent to the shoreline can contribute household debris from high winds and rainfall. Barges which move garbage from one place to another may lose material overboard when they encounter rough weather at sea or transfer their loads to land-based facilities.

Driftwood comes from trees, old piers, jetties and boats which continue to lose pieces of material as their structures decay. Heavy rains in older cities create sewer overloads which bypass the sewage treatment process and carry litter directly to the water. Trash left on the beach can be carried back to the ocean by extremely high tides and wind.

Ships and boats of all types dump garbage over the side. Large commercial and military vessels can generate tons of waste in a single day. In 1975, the National Academy of Sciences estimated that people aboard ships dispose of over 6.4 billion pounds of garbage worldwide each year. Commercial fishermen discard old nets while recreational boaters throw away monofilament line.

*What happens to **Marine Debris**?*

Marine debris is transported by currents and wind. The size and weight of the material determines where it eventually ends up. Lighter objects such as plastic cups and floating aluminum cans are strongly affected by wind. Heavier debris such as driftwood is influenced by surface currents. Storms concentrate these materials in lines of debris which wash up on beaches and shorelines.

Organic material such as food waste and wood are broken down by natural processes. Discarded food items decay faster than wood and paper, but these items will eventually decompose. Synthetic materials such as plastic remain in the environment essentially unchanged for long periods of time. Plastics are made up of long chains of molecules which are very difficult to break apart. After prolonged exposure to sunlight, some plastics become brittle and break into smaller fragments.

*What problems are caused by **Marine Debris**?*

The most offensive problems caused by marine debris are the potential harm to marine life and shore birds and

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the ugliness created by littered beaches and waterways. Trash and garbage destroy the natural beauty of shorelines and can create health hazards as well. The loss of aesthetic value can translate into loss of economic value as fewer people are attracted to coastal resorts.

Marine life and shorebirds have been injured and killed by several forms of marine debris. Fragments of synthetic fishing net have entangled fish and sea turtles. Lost crab and lobster pots continue to capture animals for long periods of time (this is called "ghost fishing"). Discarded fishing line and six pack rings entangle birds and impair their ability to feed. Sea turtles have been known to mistake plastic garbage bags for jellyfish (a food source) and have suffocated after ingesting them.

Commercial and recreational interests are also negatively impacted by marine debris. Fisheries may be harmed by abandoned nets. Plastic sheets can clog the cooling water intakes of boats and polypropylene line may become wrapped around propeller shafts. Floating pilings are especially hazardous to smaller recreational boats which can be severely damaged by collision with these objects.

*What is being done about **Marine Debris**?*

The Environmental Protection Agency (EPA) has been working with other federal agencies, states, local governments and private groups in a variety of ways to control floatable debris. Efforts are being undertaken to rehabilitate aging sewer lines and reduce combined sewer overflows. Landfill operations are being inspected and monitored more closely. In some cases, a floating boom is being used to contain refuse which falls off of barges during transfer operations. Use of barge covers is also being explored.

EPA has recently implemented stricter conditions for vessels which collect driftwood and burn it at sea. These vessels must be equipped with stanchions to contain their load and be followed by another boat to retrieve wood lost overboard. Studies are being conducted to identify sources of marine debris and ways to control them. Research is focusing on the impact of marine debris on fish and wildlife populations.

Use of degradable plastics is being evaluated as an alternative to currently used materials which break down extremely slowly. A new law will take effect in December of 1988 which prohibits commercial and military ships from disposing of plastics at sea. The U.S. Coast Guard will be responsible for enforcement and public vessels will have to abide by the same restriction by 1993.

*What can you do to reduce **Marine Debris**?*

Several coastal communities have organized cleanup activities for their shorelines and beaches. COASTWEEKS '88 is a nationwide cleanup scheduled for September 17 - October 10, 1988. Volunteers will collect trash and tally items on a scorecard. The data from all of the cleanups will be compiled by the Center for Environmental Education to establish a National Beach Cleanup Data Base.

YOU CAN HELP REDUCE MARINE DEBRIS BY:

- not littering
- minimizing the use of disposable materials
- requesting paper bags when grocery shopping
- using paper bags instead of plastic for garbage
- recycling aluminum cans and newspapers
- encouraging neighbors to recycle
- organizing a beach cleanup in your area
- encouraging local governments to institute recycling programs and repair aging sewer systems

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FACT SHEET

SECTION 301(h)

OF THE CLEAN WATER ACT

OMEP

Office of Marine and Estuarine Protection

Office of Water

*What is Section **301(h)**?*

Section 301(h) refers to a section in Title III of the Clean Water Act. Specifically, 301(h) is the section which allows for waivers of secondary treatment by publicly owned treatment works (POTWs) which discharge into marine/estuarine waters. 301(h) lists the criteria which must be met to be eligible for a waiver and describes the environmental setting where such permits are allowed.

*Background of **301(h)**:*

Until the passage of the Clean Water Act in 1972, there was little progress made in cleaning up the nation's waters. The Act allowed the Environmental Protection Agency (EPA) to establish technology based treatment requirements for sewage treatment plants. EPA established "secondary" treatment as the "best practicable control technology" and set deadlines for coming into compliance with the secondary treatment requirement.

Several west coast municipalities proposed the enactment of section 301(h) in 1977. Their proposal was based on the "assimilation capacity" of ocean waters. Because oceans have much greater mixing zone and circulation, it was argued that they could assimilate wastes more effectively than streams or rivers. Coastal municipalities felt that discharging sewage into marine waters should be regulated differently for this reason.

The waiver of secondary treatment was a return to a water quality based approach to water pollution control. In considering the mixing capacity of the ocean, receiving water quality was a criterion rather than the technology available for treatment. A great deal of controversy surrounded this approach.

*What are the criteria for a **301(h)** waiver?*

Amendments to the Clean Water Act in 1987 revised and added to the list of criteria which must be met to obtain a 301(h) waiver. These statutory criteria are summarized below:

1) There is an applicable water quality standard specific to the pollutant for which the waiver is sought.
2) The discharge will not interfere with attainment of water quality that supports a balanced indigenous population of shellfish, fish, and wildlife, and allows recreational activities.
3) Establishment of a system to monitor the impact on aquatic biota to the extent practicable.
4) There will be no increased treatment requirements on other point or nonpoint sources as a result of the waiver.
5) Applicable pretreatment requirements will be enforced.
6) For treatment works serving a population of 50,000 or more, with respect to any toxic pollutant introduced by an industrial discharger for which there is no pretreatment requirement, the treatment works must remove the same amount of such pollutant as if required to use secondary treatment.
7) Establishment of a schedule of activi-

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ties to eliminate introduction of toxics from nonindustrial sources, to the extent practicable.

8) There will be no new or substantially increased discharge above the volume specified in the permit.
9) At the time the waiver becomes effective, the treatment works will be performing at least primary treat ment or the equivalent of primary treatment.

*How are decisions made about granting **301(h)** waivers?*

Decisions are made by a consensus building process through task force recommendations. An approval process takes place within EPA whereby interagency offices review the programs. Once concurrence is achieved, the program is delegated to the EPA regional office. Another concurrence process takes place at the regional level involving the affected section, branch, division, and regional administrator. The final decision on whether or not to grant a 301(h) waiver involves public review and comment.

***301(h)** program status as of August, 1988:*

- 249 applications have been received for 301(h) waivers.
- Final decisions have been made on 185 applications.
- A total of 47 waivers have been granted.
- EPA has issued 15 guidance documents for implementation of the program.

*Future outlook for the **301(h)** program:*

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